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BIOMET
MANUFACTURING CORP.

510(k) Summary

510(k) Number: K090473

Preparation Date: March 24, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0578

Proprietary Name: Discovery™ Elbow – X-Small

Common Name: Elbow Prosthesis

Classification Name: Elbow joint metal/polymer constrained cemented prosthesis (21 CFR 888.3150)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: The predicate device is the Discovery™ Elbow, originally cleared through 510(k) K013042, on October 10, 2001 and modified on through 510(k) K051975 cleared on September 6, 2005.

Device Description: The Discovery™ Elbow is a total elbow prosthesis comprised of an ulnar and humeral component. Placing the humeral articulation through the ulnar articulation links the ulnar and humeral component. The humeral components are available with or without a flange. The numeral and ulnar components are avialalbe with either a smooth or roughened surface. The components contained in this submission are X-Small in size.

Intended Use: The indications for use for the Discovery™ Elbow – X-Small include:
1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2. Rheumatoid arthritis,
3. Revision where other devices or treatments have failed,
4. Correction of functional deformity,

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5. Treatment of acute or chronic fractures with humeral epicondyle involvement, which are unmanageable using other treatment methods.

The device is intended for use with bone cement.

Summary of Technologies: The Discovery™ Elbow X-Small has similar or identical technologies to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corp.
% Ms. Patricia Sandborn Beres
P.O. Box 587
Warsaw, Indiana 46581-0578

MAR 2 5 2009

Re: K090473
Trade/Device Name: Discovery Elbow – X-Small
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: February 20, 2009
Received: February 24, 2009

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090473

Device Name: Discovery Elbow – X-Small

Indications For Use: The Discovery Elbow – X-Small is intended for cemented use in patients with the following conditions:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
2. Rheumatoid arthritis,
3. Revision where other devices or treatments have failed,
4. Correction of functional deformity,
5. Treatment of acute or chronic fractures with humeral epicondyle involvement, which are unmanageable using other treatment methods

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K090473